

# EXHIBIT

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**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

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**IN RE: ETHICON, INC. PELVIC REPAIR  
SYSTEM PRODUCTS LIABILITY LITIGATION**

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**Master File No. 2:12-MD-02327  
MDL 2327**

**THIS DOCUMENT RELATES TO:**  
*Melinda Geisinger v. Ethicon, Inc., et al.*  
*2:12-cv-05112*

**HON. JOSEPH R. GOODWIN**

**RULE 26 EXPERT REPORT OF DR. WILLIAM PORTER, M.D.**

**A. Qualifications and Background.**

My name is William Edward Porter, M.D. I received a bachelor's degree in biology at the University of Michigan located in Ann Arbor, MI. I then went on and obtained a medical degree from the Wayne State University located in Detroit, MI. I subsequently completed a residency in obstetrics and gynecology at the University of Cincinnati and an American Board of Obstetrics and Gynecology certified three-year fellowship in Female Pelvic Medicine and Reconstructive Surgery (FPMRS) at the University of Tennessee Medical Center located in Memphis, Tennessee. I am one of the first ABOG Certified Physicians in the United States in the Field of (FPMRS). I served as a reviewer for the International Urogynecology Journal (2003 to 2006). I am currently a journal reviewer for Female Pelvic Medicine & Reconstructive Surgery. I serve on the American Urogynecology Society Coding Committee (2012 to 2016). I have lectured locally, nationally, and internationally on many subjects in the field of urogynecology and reconstructive pelvic surgery, including pelvic organ prolapse and urinary incontinence. I have taught at many medical device industry sponsored labs, the purpose of which has been to instruct other surgeons on the proper use of surgical devices and tools to treat pelvic organ prolapse and stress incontinence. I have also worked as a consultant to many medical device companies in developing and validating new products in the pelvic floor space.

I am trained extensively and practice exclusively in the field of pelvic medicine. This field encompasses pelvic organ prolapse, urinary incontinence, fecal incontinence, pelvic pain and pelvic floor dysfunction. Over the past 14 years post residency, I have performed nearly

3,000 pubovaginal slings (synthetic and xenographic) and fascia latta bladder neck slings. I have performed several thousand vaginal repairs for pelvic organ prolapse using native tissue, allograph, xenograph or synthetic augmented repairs. In the same regard I have also removed slings and mesh complicated surgeries (erosion and/ extrusion).

I have been specifically trained to use pelvic organ products (slings, graphs and mesh kits) by the following companies: C. R. Bard, Boston Scientific, Mentor, Cook Medical, Gynecare, American Medical System and Coloplast. I did complete any training required by said companies. I have been a trained proctor for the following companies: C.R. Bard, Boston Scientific, Mentor, Cook Medical, Gynecare and Coloplast. I have specifically treated female patients with the TVT mid-urethral sling.

Based upon my work as a urogynecologist (FPMRS), I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants and mid-urethral slings. The focus of my evaluation is the role that the TVT played in causing injury to Ms. Geisinger. The most common mesh-related complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, chronic vaginal discharge or bleeding, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion of mesh into tissues or organs, and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the likely cause of the patient's complications based upon a differential diagnosis, which typically includes a physical and history and a review of her medical records and other information about the patient.

In formulating the opinions set forth in this report I have relied on my personal knowledge, education and training, prior experience in treating stress urinary incontinence, medical literature, and a review of relevant medical records pertaining to Ms. Geisinger. All of my opinions are true and correct to the best of my knowledge. I do reserve the right to supplement this report and my opinions if additional information becomes available (reports, discovery, articles or other relevant information). I also reserve the right to perform a physical examination on Ms. Geisinger.

#### **B. Summary of Materials Reviewed.**

I have reviewed the following medical records and depositions with accompanying exhibits pertaining to Melinda Geisinger:

Altru Health System

Grafton Family Clinic

Unity Medical Center

Riverview Health Clinics

Northern Valley Ob Gyn

Deposition of Melinda Geisinger

Plaintiff Profile Form and Plaintiff Fact Sheet of Melinda Geisinger

**C. Summary of Medical Facts related to Melinda Geisinger**

**DOB: 4/16/1963**

**Past Medical History**

Obesity, Depression, Anxiety, Gastric reflux, Hyperlipidemia, Sleep Apnea, Schizophrenia, IBS, Arthritis, Endometriosis, Chronic Abdominal Pain, Medullary Sponge Kidney with kidney stones

**Past Surgical History**

Bunionectomy, Hysterectomy, Cholecystectomy, TVT, Gastric Sleeve

**Medications**

Celexa, Benadryl, Premarin, Ativan, Zantac, Zocor, Mellaril, Artane

**Social**

No smoking

**12/31/2001**

She presents with complaints of abdominal pain.

**3/20/2003**

She presented for her annual examination. She reports stress incontinence.

**4/8/2003**

She presented for complaints of stress incontinence after the birth of her child 2 years prior.

**3/23/2004**

She reports again stress incontinence and wanted conservative therapy.

**10/9/2005**

She reports left flank pain. She reports pain that radiates into her groin.

**11/11/2005**

She reports abdominal pain and she was diagnosed with IBS

**7/26/2005**

She denies any GYN symptoms.

**8/17/2007**

She is s/p pelvic floor physical therapy. She complains of frequency and urgency.

**2/18/2008**

She has had increased urinary incontinence. She is wearing a pad and causing social embarrassment. She had a prolapse of her bladder walls.

**3/6/2008**

She reports urinary frequency with the need to wear a pad daily. She had a second degree rectocele.

**3/12/2008**

She presented with right upper quadrant pain. She reports 10/10 pain. She also has some urinary frequency and urgency.

**4/7/2008**

LAVH with BSO

**6/2/2008**

She had a recent laparoscopic hysterectomy for long history of pelvic pain and endometriosis. She reports stress incontinence that happen before her LAVH. She had a TVT placed.

**6/19/2008**

She is 2 weeks past TVT placement. She reports that she did have sex within the first 2 weeks. Kathy Detke WHNP spoke with the nurse (Mary Jo) about the recent fixation on her GYN care. Melinda reports that it is anxiety related.

**8/10/2008**

She is s/p a TVT-sling. She reports dysuria and difficulty emptying her bladder.

**9/11/2008**

She had a cystoscopy due to chronic UTIs. She has urethral syndrome.

**8/10/2009**

She was seen for vaginal bleeding.

**6/18/2010**

She reports dysuria. She has history of recurrent UTIs. She had been seen earlier in the day with an elevated PVR of 200 ml. She was treated for an UTI.

**2/9/2011**

She has UTIs symptoms but negative urinalysis. She was diagnosed with an urethral syndrome and bladder neck spasms.

**9/29/2011**

She was seen in the ER for abdominal and flank pain on unknown etiology.

**3/1/2011**

She had a cystoscopy with urethral dilation. She had bladder tenderness on her bladder neck. She had bladder inflammation on cystoscopy.

**3/16/2011**

She was seen by Dr Schultz for follow up evaluation from cystoscopy. She had bladder neck tenderness and was difficult to exam while the patient was awake. She was found to have mesh exposure and he felt this was a source of her pain.

**3/21/2011**

Excision of the pubovesical sling that erode across her bladder neck.

**6/29/2011**

She reports that she is not emptying her bladder. She reports her burning has resolved. Her PVR are now 70 ml vs 140 ml. She was diagnosed intractable overactive bladder syndrome. She was offered Urgent PC vs Interstim.

**2/16/2012**

She reports left obturator pain which had improved initially with antibiotics. The pain has increased. She had pinpoint pain over her left obturator. And extends back towards midline.

**3/12/2012**

She had a prior "Avaulta mesh anteriorly with ongoing obturator pain". This is the TVT per other records. She was diagnosed with erosion of the tail of the mesh on the left.

**2/29/2012**

She presents to the ER for low abdominal pain. She thinks it is probably her bladder. She had a sling placed in 2008 by Dr. Trottier. It was removed on 2011. She reports that the product was recalled. She was seen by Dr. Schultz and thinks there is 1 cm left. She reports that she may be retaining urine.

**6/19/2012**

She has continuous right lower quadrant pain. She has concerns about a recurrence of her endometriosis. She denies dyspareunia. She has increased frequency.

**7/12/2012**

She presented with right sided numbness. She had a normal CT.

**11/8/2012**

She had abdominal pain and presented to the ER.

#### **D. Methodology and Analysis.**

In determining the cause of a specific injury, it is customary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause. This process is known as differential diagnosis, or differential etiology, and it is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I often determine the cause of a patient's complications based upon an interview with the patient, a review of her medical records or knowledge of her prior medical history. I have used that methodology in arriving at my opinions in the case.

During her visits she reports having dyspareunia that prevented her from coitus. Meyer et al reports dyspareunia rates of 36% at a 5 year follow up from mesh surgery. On the other hand, Alperin et al reports a dyspareunia rate of 28.9%, which was similar to preoperative rate. Porter et al reports a site-specific posterior repair tends to have a positive effect on dyspareunia 73% cured vs. 19% where it increased. It appears that TVT may have a negative effect on coitus and thus complicating Ms. Geisinger health.

As the vagina is a cleaned contaminated area, there is no way to completely eliminate bacteria from the surgical site. Implantation though this dirty field could allow bacteria to attach. These bacteria then can attach to the mesh and secrete a biofilm or a polysaccharide slime excreted by the bacteria. This slime could prevent the host defensive mechanism from clearing the infection. (Edmiston). This tissue response can contribute to the cause of vaginal pain, pelvic

pain and chronic inflammation. This chronic inflammation/infection could be a source of pain. This chronic inflammation/infection could be a source of an erosion, vaginal discharge and possible UTI's. Dr. Daniel Elliott in his general expert report suggested the mesh creates a foreign body reaction and a chronic inflammatory response that can lead to chronic pain in the patient. The body's foreign body response to the mesh can cause a severe and chronic inflammatory reaction leading to excessive scarring in and around the mesh. Dr. Bruce Rosenzweig of the general expert witness group suggests that mesh degrades over time and causes a chronic foreign body reaction, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, roping and curling of the mesh contributing to pain. Ethicon's Daniel Burkley, a Principal Scientist has testified that polypropylene mesh in human beings is subject to some degree of surface degradation

In considering the cause of the vaginal pain and dyspareunia suffered by Melinda Geisinger, her TVT sling contributed to her pain and vaginal scarring. Dr Rosenzweig's suggesting that mesh causes at chronic inflammation which in turn results in pain and exposure.

The next step in my analysis was to rule out other potential causes. I did consider other potential causes including post-op scarring and granulation tissue from her hysterectomy and cholecystectomy. I also considered other factors in her history including her previous pelvic surgery, gastric reflux, irritable bowel syndrome, kidney stones, endometriosis and chronic abdominal pain. She had participated in physical therapy prior to her surgery for urinary symptoms as well as pain. She was diagnosed recurrent UTIs but was discovered on cystoscopy to have urethral syndrome and bladder neck spasms which can mimic UTIs. She was also diagnosed with intractable overactive bladder which can cause pelvic and abdominal pain I considered each of these other risks for her pain and dyspareunia and I concluded that they could be ruled out as a source of her vaginal pain suffered by Melinda Geisinger.

Additionally, it is my opinion to a reasonable degree of medical and scientific certainty, based on my background, education, training and experience, that Melinda Geisinger treating physicians who implanted met the standard of care during implantation of the device. I found no evidence of surgical error or deviation from the requisite procedural steps. Further, after reviewing the operative reports, I see no evidence of any surgical complications.

#### **E. Conclusion.**

Based on the foregoing analysis, and based on my education, training and knowledge, it is my opinion to a reasonable degree of medical probability that the cause of Ms. Geisinger's pelvic pain and mesh exposure is related to her TVT- Mesh Implant. This pain is related to what Dr Elliott described as a chronic inflammation around the mesh.

I have the right to supplement and amend this opinion should additional factual information be forwarded to me that I did not have available at the time this opinion is submitted.

Dated this the 7<sup>th</sup> day of January 2017

A handwritten signature in black ink, appearing to be 'W. Porter', written over a horizontal line.

William Porter, M.D.